# Summary of Safety and Effectiveness

JUN 10 2014

Date: June 11, 2014

Manufacturer:
Limacorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine - Italy

U.S. Contact Person:
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| Product | Common Name | Product Code | Regulation and Classification Name |
|---|---|---|---|
| Master$^{SL}$ femoral stem | Total or Hemi Hip Prosthesis | LZO | Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353 |
| | | JDI | Hip joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3350 |
| | | KWY | Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis per 21 CFR 888.3390 |
| | | KWZ | Prosthesis, Hip, Constrained, Cemented Or Uncemented, Metal/Polymer per 21 CFR 888.3310 |
| | | LPH | Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemente per 21 CFR 888.3358 |

**Description:**

The Master$^{SL}$ femoral stem is a monolithic, collarless, tapered wedge shaped stem intended for press-fit uncemented partial or total hip arthroplasty. When used in total hip arthroplasty the stem is coupled to a Limacorporate Femoral Heads (K112158) and used with either a Limacorporate Cemented Cups (K112158) or Limacorporate Delta TT Acetabular System cup (K112898). When used in partial hip arthroplasty the Master$^{SL}$ femoral stem is coupled to a Limacorporate Femoral Heads (K112158) and used with a Lock Bipolar Head (Limacorporate K112158).

The Master$^{SL}$ femoral stem is made of Ti6Al4V alloy conforming to ASTM F1472 – ISO 5832-3; the proximnal ½ of the stem a plasma sprayed coating of titanium alloy (ASTM F1472 – ISO 5832-3). The stem has a tapered rectangular section and the distal anterior and posterior surfaces have a vertical groove for rotational stability. The stem provides a

neck with a 12/14 conical taper to couple to Limacorporate Femoral Heads and the necks are mirror-polished and lowered to reduce accidental abrasion and contact between the stem neck and the acetabular cup. The Master$^{SL}$ stems is available 13 sizes in both standard and lateralized versions with different CCD angles.

**Intended Use:**

The Master$^{SL}$ stems are indicated for use in partial or total hip arthroplasty and are intended for press-fit (uncemented) use. When used in total hip arthroplasty, the MasterSL Stems are intended for use with Co-Cr-Mo femoral heads and cemented cups or with Co-Cr-Mo femoral heads and Delta TT Acetabular System. When used in partial hip arthroplasty, the MasterSL stems are intended for use with Lock Bipolar Heads.
Hip arthroplasty is intended for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis and hip dysplasia;
- rheumatoid arthritis;
- treatment of femoral head and neck fractures;
- revisions in cases of good remaining femoral bone stock.

**Predicate Devices:**

- H-MAX S stems (Limacorporate, K112091):
- Encore Linear Hip (DJO, K972791 and K991325);
- Modulus Femoral Hip System (Limacorporate, K112158);
- Taperloc 12/14 Taper Femoral Component (BIOMET, K043537).

**Comparable Features to Predicate Device(s):**

The Master$^{SL}$ stems are substantially equivalent to the predicate devices in terms of intended use, indications for use, design and materials. As for all of the predicates, the Master$^{SL}$ stems is intended for use in total hip arthroplasty and like the Modulus Femoral Hip System predicate (K112158), it can also be used in partial hip arthroplasty. Like all of the predicates, the subject MasterSL stem is intended for press-fit cementless use.

The Master$^{SL}$ stems are manufactured from the same materials as the predicate devices. The Master$^{SL}$ stem has a tapered wedge design which is similar to all of the predicates exception that predicate Modulus stem is a 2-piece stem with the components coupled through a conical taper while the other predicates and the subject device are all one pice monolithic stems. Like all of the predicates, the subject device is available in standard and lateralized versions, with different CCD angles, offsets and sizes.

**Non-Clinical Testing:**

The Master$^{SL}$ stems were tested in worst case configurations for fatigue resistance according to ISO 7206-4 and ISO 7206-6.

The ROM of the Master$^{SL}$ hip stem was analyzed using the worst case construct.

The Titanium Plasma Spray coating was characterized to verify the conformity to FDA guideline and referenced standards.

**Clinical Testing:**

Clinical testing was not necessary to demonstrate substantial equivalence of the Master$^{SL}$ Femoral Stem to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 10, 2014

Limacorporate S.p.A.
% Stephen Peoples, VMD
President
Peoples and Associates Consulting LLC
5010 Lodge Pole Lane
Fort Wayne, Indiana 46814

Re: K140975
Trade/Device Name: Master$^{SL}$ Femoral Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, JDI, KWY, KWZ, LPH
Dated: February 25, 2014
Received: April 16, 2014

Dear Dr. Peoples:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K140975
Device Name: Master$^{SL}$ Femoral Stem
Indications for Use:

## MasterSL Femoral Stem
## Indications for Use

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- rheumatoid arthritis;
- treatment of femoral head and neck fractures;
- revisions in cases of good remaining femoral bone stock.

| Prescription Use X (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
|---|---|---|

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Elizabeth L. Franks

Division of Orthopedic Devices